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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,421	11/21/2003	John Eric Peckham	S63.2-11294-US01	3394

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EXAMINER	
CHENG, JACQUELINE	

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
09/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,421	PECKHAM, JOHN ERIC	
	Examiner	Art Unit	
	JACQUELINE CHENG	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27,36 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27,36 and 37* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed April 14, 2009, with respect to the rejection(s) of claim(s) under Lee (US 5,203,777) in view of Kitrell (US 4718,417) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, various new ground(s) of rejection have been made.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Page 10 line 15 of the specification states that fig. 4 has sheath 50. The label --50-- for the sheath is missing in fig. 4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 1-14, 24-27, and 36** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Description of the marker wire being *permanently* coupled to the medical device was not found in the specification.

5. **Claims 9-12 and 14** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is not described in the specification how the applicant has a marker wire permanently coupled to the medical device of a stent or an expansion balloon. Furthermore the applicant argues on page 17 and 18 of the appeal brief filed April 14, 2009 that a person of ordinary skill in the art would recognize that a marker placed directly on a stent or expansion balloon would interfere with the stent's and/or expansion balloon's ability to expand, or expansion of the stent and/or expansion balloon would skew and deform the wire marker outlines such that they would no longer be capable of conveying the rotation orientation of the stent or of the expansion balloon, implying that if the marker wire of the current invention was permanently coupled to the stent or expansion balloon it would have the same alleged problems.

Claim Rejections - 35 USC § 102

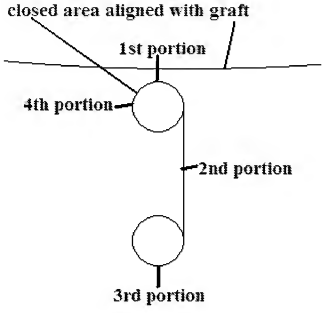
6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 1-6, 12, 13, 24, and 25** are rejected under 35 U.S.C. 102(e) as being anticipated by Hyde (US 6,957,098 B1). Hyde discloses using an active marker wire to locate any medical device such as a catheter, a balloon catheter, a drug delivery catheter (has a lumen and port) (col. 12 line 64-5). The marker wire of Hyde has two portions (first portion and third portion) extending in a circumferential direction and two portions (second portion and fourth portion) extending in a direction parallel to the longitudinal axis of the medical device. The marker wire is continuous closed circuit (fig. 3a, 3b). Although Hyde does not disclose the marker is used for determining rotational orientation or that the lumen is arranged to carry away bodily material the prior art fulfills all the structural limitations of the claims. If the marker was to be imaged using an x-ray device the rotation of the device can be determined using current configuration of the marker wire in Hyde and the lumen is capable of being arranged to carry away bodily material.

8. **Claims 1-5, 8-11, and 14** are rejected under 35 U.S.C. 102(b) as being anticipated by Lombardi (US 5,824,042). Lombardi discloses a marker attached to a medical device such as a

stent or a stent-graft. The marker extends such that two portions (first portion and third portion) extends in a circumferential direction and two portions (second portion and fourth portion) extending in a direction parallel to the longitudinal axis of the medical device forming a continuous closed circuit (fig. 10a, 10b, and below). Furthermore the top of the graft is aligned with the closed area defined by the marker wire.



Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. **Claims 1-6, 13, 24, 25 and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower'311 (US 6,579,311 B1) further in view of Makower'875 (US 6,302,875 B1). Makower'311 teaches a catheter comprising a lumen and a port with a passive marker that has two portions (first portion and third portion) extending in a circumferential direction and two portions (second portion and fourth portion) extending in a direction parallel to the longitudinal axis of the medical device to form a continuous closed circuit (fig. 3c, 3d). The catheter is inserted into a bodily lumen and maneuvered to a desired location. Once placed in a desired location the device is rotated until the operator sees that the marker is aligned properly (col. 10 line 1- 22). The passive marker device can be created using any known set of materials which would allow for radiographic, fluoroscopic, magnetic, sonographic, or electromagnetic detection of the position and orientation of the device (col. 9 line 6-10) so it would be obvious to use any well known material such as disclosed by Makower'875. Makower'875 discloses using wire to form an imagable marker (col. 16 line 23-24).

11. **Claim 27** is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower'311 in view of Makower'875 further in view of Plaia (US 6,497,711 B1). Makower'311 discloses that the catheter device is used as an access port through which a procedure may be performed such as ablating a volume of tissue. It would be obvious to use any well known device with the catheter device of Makower'311 depending on the procedure desired to be performed such as using a rotating ablation device as disclosed by Plaia (abstract) if an ablation of tissue was desired to be performed.

12. **Claims 1-7, 12, 15, 16, 18-20, 23-25, and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower'875. Makower'875 teaches markers that can be used in conjunction with any passageway-forming catheters such as catheters, catheter sheaths, and balloon catheters with lumens and ports (abstract, col. 25 line 46-67). The passive marker has two portions (first portion and third portion) extending in a circumferential direction and two portions (second portion and fourth portion) extending in a direction parallel to the longitudinal axis of the medical device which forms a continuous closed circuit (fig. 6b element 124) as well as a first directional indicator (fig. 6b element 200) and a second directional indicator (fig. 6b element 126) offset from the first directional indicator which forms a symbol of a target and R when viewed at a proper rotational orientation (the symbol is viewable over a rotational range of 5 degrees) to help in determining a rotational orientation of the device. The catheter is inserted into a bodily lumen and maneuvered to a desired location and then using the marker symbols, is rotated to the desired rotational orientation (col. 1 line 25-col. 2 line 20, col. 15 line 8-18). Makower'875 discloses that the markers of fig. 6b be made from radiopaque materials so it would be obvious to use any well known radiopaque material such as a metal wire as previously disclosed in Makower'875 (col. 16 line 23-24).

13. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower'875 in view of Makower'311. Makower'875 discloses most of what is claimed as disclosed above except for the first and second directional indicator forming an arrow symbol. Makower'311 discloses the same type of rotational orientation marker devices wherein only three different embodiments as shown, however any other geometrical designs may be provided such that when visualization of a particular geometry occurs, it may be said that a proper orientation of the

device has been achieved, or even non-geometrical makers can be used as long as it provides proper orientation of the device (col. 10 line 50-59). Therefore it would be obvious to use a well known geometric shapes such as angular lines which forms a particular geometry of an arrow. Furthermore the shape of the marker device is a design choice as both provide the same function of determining proper rotational orientation of a device.

14. **Claims 15, 19, 20, and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Armstrong (US 2002/0099431 A1) in view of Makower'875. Armstrong discloses a stent which is covered by a partial graft wherein the stent graft is aligned with a radiopaque marker. Armstrong does not explicitly disclose what type of radiopaque marker is used. It would be obvious to use any radiopaque marker such as disclosed in Makower'875 as discussed above.

15. **Claims 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower'875 in view of Nash (US 2002/0032432 A1). Makower'875 discloses most of what is claimed except for the symbol being an arrow. It would be obvious to use any type of rotational indicator such as an arrow instead of the "R" as disclosed by Makower'875 as the style of rotational indicator is a design choice and using an arrow as a rotational indicator is well known in the art such as disclosed by Nash. Nash discloses using an arrow symbol as a rotational indicator (fig. 1 element 38, paragraph 0036).

16. **Claims 1-6 and 24-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty (US 6,660,024 B1) in view of Makower'875. Flaherty discloses a medical device such

as a catheter having a lumen and port that has a marker for determining rotational orientation of the device. The marker comprises two portions (first portion and third portion) extending in a circumferential direction and two portions (second portion and fourth portion) extending in a direction parallel to the longitudinal axis of the medical device which forms a continuous closed circuit (fig. 3f). The marker surrounds an imaging transducer which is positioned closely adjacent to an exit port rendering the marker extending about a rim of the port. Furthermore in another embodiment the exit port is located directly at the point at which the transducer is affixed rendering the marker extending around and surrounding the rim of the port (col. 9 line 19-60). Flaherty does not explicitly disclose what the marker is made of. It would be obvious to use any well known radiopaque marker well known in the art such as wire as disclosed by Makower'875 (col. 16 line 23-24).

17. **Claim 36** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis (US 6,416,490). Ellis teaches a marker (fig. 15 element 304 or fig. 18 element 306) coupled to a medical device to determine a rotational orientation of the device. The marker has a first end and a second end offset from each other along the length of the device and in a circumferential direction. Ellis teaches that the marker is a radiopaque marker formed of gold or platinum but does not disclose the form of the radiopaque marker. It would be obvious to use any well known radiopaque marker well known in the art such as wire as disclosed by Makower'875 (col. 16 line 23-24).

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,723,116 B2 to Taheri, US 5,741,327 to Frantzen, US 6,726,677 B1 to Flaherty, US 6,685,648 B2 to Flaherty, US 4,693,237 to Hoffman, US 6,083,167 to Fox and US 2003/0167052 A1 to Lee.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768